GOVERNMENT OF INDIA

BHARAT SARKAR

MINISTRY OF HEALTH AND FAMILY WELFARE

SWASTHYA AUR PARIVAR KALYAN MANTRALAYA

REPORT OF THE CENTRAL DRUGS LABORATORY CALCUTTA

1ST APRIL 1974 TO 31ST MARCH 1977

GOVERNMENT OF INDIA

BHARAT SARKAR

COMMUNITY HEALTH CELL
326, V Main, I Block
Koramangala
Bangalore-560034
India

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STAFF

Director	Dr. D. Ghosh, Ph.D., F.R.I.C. (Lond) (Up to 31 January, 1976)
Director (Actg.) & Deputy Director .	Dr. R. Chanda, Ph.D. (Glasgow), C. Chem., F.R.I.C. (Lond), (from 1st February, 1976).

Section of Pharmaceutical Chemistry

Pharmaceutical Chemist .	Shri A.P. Bhattacharya, M.Sc. (Retired on 31-12-75).
	Shri B. Mondal, M.Sc. (from 2-1-76)
Associate Pharmaceutical Chemist .	Shri R.P. Chakraborty, B.Sc.
	Dr. A.C. Das Gupta, Ph.D.
Technical Officer (Pharm. Chemistry)	Dr. P.C. Bose, Ph.D.
Research Assistant . . .	Shri J.N. Mukherjee (expired on 29-5-74)
(Pharmaceutical Chemistry)	Shri B.N. Sarkar
	Shri C.L. Choudhury
	Smt. P. Bhattacharya (from 24-6-76)
	Shri B.N. Das (from 17-3-77)

Section of Biochemistry

Biochemist	Dr. S.C. Sharma, Ph.D. (from 7-1-74)
Associate Biochemist . . .	Dr. V.K. Madan (from 20-10-75 to 30-11-76)
Technical Officer (Biochemistry) .	Shri S.K. Rudra, B.Sc.
Research Assistant (Biochemistry) .	Shri S.K. Chatterjee
	Shri P.K. Sengupta (from 17-3-77)
	Shri S.N. Sarkar (from 17-3-77)

Section of Pharmacology

Technical Officer (Pharmacology) .	Dr. Jaladhar Saha, Ph.D. (upto 10-3-77)
Associate Pharmacologist .	Dr. (Mrs.) Dipali Roy, Ph.D.
Senior Scientific Asstt. (Pharmacology)	Shri A.K. Khasnobis (from 16-10-76)

Section of Bacteriology

Bacteriologist	Dr. M.K. Majumdar, D.Sc.
Associate Bacteriologist . . .	Shri S.K. Mukherjee, B.Sc.
Technical Officer (Bacteriology) .	Shri P.G. Ray, M.Sc.
Senior Scientific Assistants (Bacteriology).	Shri R.K. Acharya (from 16-1-76) Redesignated.
	Shri P.R. Bhattacharya (from 16-10-76) Redesignated

Section of Pharmacognosy

Associate Pharmacognocist: . .	Dr. V.K. Mudgal, Ph.D. (from 12-2-76)
Research Assistant (Pharmacognosy) .	Shri G.K. Munshi (from 17-3-77)
Office Superintendent . . .	Shri S.K. Bhattacharya (from 11-12-72 to 30-11-75)
	Shri K.K. Dutta (from 1-12-75 to 31-3-77).
Stenographer Gr. I . . .	Shri M.L. Mukherjee, B.A.,B.L.

1. INTRODUCTION

The present report covers the period from 1st April 1974 to 31st March 1977 (financial years 1974-75, 1975-76 and 1976-77).

The Central Drugs Laboratory, Calcutta, is the national statutory laboratory of the Government of India for quality control of drugs and cosmetics and is established under the Indian Drugs and Cosmetics Act, 1940. It is the oldest quality control laboratory of the Drugs Control Authorities in India. It functions under the administrative control of the Director-General of Health Services in the Ministry of Health & Family Welfare.

2. FUNCTIONS

2.1 Statutory Functions

(a) Analytical quality control of majority of the imported drugs available in the Indian market.

(b) Analytical quality control of drugs and cosmetics manufactured within the country on behalf of the Central and State Drug Control Administrations.

(c) Acting as an Appellate Authority in matters of disputes relating to quality of drugs.

2.2 Other Functions

(a) Collection, storage and distribution of International Standards, International Reference Preparations of drugs and Pharmaceutical Substances.

(b) Preparation of National Reference Standards and maintenance of such Standards. Maintenance of microbial cultures useful in drug analysis. Distribution of standards and cultures to State Quality Control Laboratories and drug manufacturing establishments.

(c) Training of Drug Analysts deputed by State Drug Control Laboratories and other Institutions.

(d) Training of World Health Organization Fellows from abroad on modern methods of drug analysis.

(e) To advise the Central Drug Control Administration in respect of quality and toxicity of drugs awaiting the grant of licence.

(f) To work out analytical specifications for preparation of Monographs for the Indian Pharmacopoeia and the Homoeopathic Pharmacopoeia of India.

(g) To undertake analytical research in standardisation and methodology of drugs and cosmetics.

(h) To undertake planned National Survey on the quality of essential drugs in collaboration with Zonal Offices of the Central Drugs Standard Control Organization.

In addition to the above functions, the Central Drugs Laboratory also actively collaborates with the World Health Organisation in the preparation of International Standards and Specifications for International Pharmacopoeia. It also undertakes collaborative study on behalf of the Indian Pharmacopoeia Committee. The senior officers of this Laboratory have been appointed as Government Analysts on behalf of most of the States of the Union for the analysis of drugs and cosmetic samples.

3. ORGANIZATION

The Laboratory has five Scientific Divisions viz. Pharmaceutical Chemistry, Biochemistry, Bacteriology, Pharmacology and Pharmacognosy. There is also a separate Division dealing with Drug Reference Standards and collection and maintenance of analytical methods, authentic specimens and reference samples of new drugs. The Government of India have also sanctioned staff for the creation of two more Sections on Toxicology and Pharmaceutical Research.

4. BUDGET

Budget provisions of the Central Drugs Laboratory, Calcutta for the three years are given below:—

Years	Non-Plan	Plan	DTAB (Plan) Training of Drug Analysts
1974-75 .	Rs. 9,00,000	Rs. 50,000	Rs. 15,000
1975-76 .	Rs. 9,52,000	Rs. 2,14,000	Rs. 32,000
1976-77 .	Rs. 9,72,000	Rs. 3,30,000	Rs. 35,000

5. STATUTORY ACTIVITIES

5.1 Testing of Samples

A total number of 5764 (excluding IDQ samples) samples of drugs were received for analysis from various sources during the period; 5634 samples were analysed, out of which 3748 (about 66.5%) were of acceptable quality (please see Appendix 1 to 6 for details).

In addition 2618 samples of essential drugs were also examined under the planned Intensified Drugs Quality (IDQ) Control programme during the period (please see para 10 for details).

5.1.1. *Imported Drug Samples*

During the period under report, 1673 samples were received from the various ports of India; 1662 samples were tested, out of which 1429 (85.9%) were found to be of standard quality. Only 228 samples were found sub-standard for not conforming to the specifications.

5.1.2. *State Drug Samples*

Samples under this category consisted mostly of formulations manufactured within the country and sent to this laboratory by the State Drug Control authorities under the Drugs and Cosmetics Act. A total of 2135 samples of drugs were received from various States, out of which 2159 samples were tested including the samples from the previous year which were also tested and 1187 samples were found to be of standard quality (about 55%) and 707 samples were of sub-standard quality (32.7%).

The number of spurious preparations detected during the period was 103 as compared to 64 during the last three year period.

Spurious drugs detected during 1974-75

Twenty eight samples of drugs were found to be spurious during 1974-75. The spurious preparations were labelled to contain the following drugs:—

(1) Analgin, (2) Betamethasone, (3) Chloramphenicol capsules, (4) Chloramphenicol Streptomycin combination capsules, (5) Glycerine, (6) Oxytetracycline Capsules and Injections,

(7) Promazine Hydrochloride Tablet, (8) Penicillin Logenzes, (9) Sodium Phosphate Injection, (10) Sulphadiazine Tablets, (11) Tetracycline Hydrochloride capsules, (12) Vitamin B Complex capsules and injections, (13) Zinc Oxide. Some of the above samples were spurious imitations of reputed manufacturers.

Spurious Drugs detected during 1975-76

During 1975-76, 28 samples of spurious drugs were detected by this laboratory. The spurious preparations were labelled to contain the following drugs: —(1) Tetracycline, (2) Chloramphenicol capsules, (3) Oxytetracycline capsules, (4) penicillin Eye Ointment, (5) Saffron, (6) Prednisolone, (7) Glycerine, (8) Sodium Antimony Gluconate Injection, (9) A.P.C. Tablet, (10) Sulphanilamide Tablet.

Spurious drugs detected during 1976-77

During 1976-77, 47 samples of spurious drugs were detected by this Laboratory. The spurious preparations were labelled to contain the following drugs:— (1) Chloroquine Phosphate Tablets, (2) Tetracycline capsules, (3) Chloramphenicol capsules, (4) Ampicillin capsule, (5) Sulphadiazine tablet, (6) A.P.C. Tablets, (7) Sulphaguanidine Tablet, (8) Glycerine, (9) Prednisolone Tablets, (10) Dexamethasone Tablets, (11) Medichemstrep, (12) Chlorostrep capsules, (13) Contracep, (14) Jirna Sudha, etc.

Fees charged to State Drug Control Authorities for testing of samples during the 3 financial years were as follows: During 1974-75: Rs. 34,630.00; during 1975-76: Rs. 18,845.00; during 1976-77: Rs. 27,045.00.

5.1.3. *Court Cases (Appellate Functions)*

Forty drug case samples were referred to this laboratory by the Courts of Law during the period under report. Out of these 35 samples were tested and 15 were found to be of standard quality. 19 samples were declared to be of sub-standard quality and no opinion could be expressed in respect of 1 sample.

5.1.4. *Samples from Central Drugs Standard Control Organisation*

A total of 1825 number of samples (compared to only 818 samples during the corresponding period of the last triennial report) were received during the period from the 4 Zonal Offices of the Central Drugs Standard Control Organisations located

at Calcutta, Bombay, Madras, Cochin and the Headquarters at New Delhi. Out of these samples 1719 were tested, compared to only 710 samples during the corresponding period of the previous triennial report, and 1063 samples were found to be of standard quality, compared to 555 samples during the corresponding period of the previous triennial report. The above figures would clearly indicate that a very large number of samples were taken care of by the C.D.L. from the CDSCO during this period.

6. ANIMAL HOUSE

The laboratory maintains a modern Animal House for research and testing. The number of animals used for research purposes and also for determination of pyrogen, toxicity, hormone assay, and other biological tests were as follows:—

Mice	2954
Rats	125
Guineapig	48
Cat	24
Rabbits	159
Toad	3

7. RESEARCH AND INVESTIGATIONAL WORK

Research and investigational work relating to analytical quality control of drugs, including standardisation of homoeopathic mother tinctures, drugs and cosmetics, were carried out during the period under report.

Investigational work included the detection of spurious fish oils by characterisation of nature of retinyl ester, and detection and isolation of diethylene glycol contamination in non-syrupy base of pharmaceutical formulations by thin layer chromatography and other physico-chemical methods.

7.1 Publications

The following scientific papers and articles were published during the period:—

1974-75

1. "On the quality control of glucose injections" by Dr. D. Ghosh, Bulletin of the Industrial Pharmacy Division, I.Ph.A. Vol, 3, No. 3 July-September, 1974, pp. 75-81.

2. "Analytical survey of Homoeopathic mother tincture for statutory quality control, Part 5, UV Absorption and TLC studies of mother tincture of Aconite" by D. D. Datta, J. Saha and D. Ghosh, The Eastern Pharmacist, Scientific Section, Vol. XVIII, No. 212, August, 1975.

1975-76

3. "The nature of Vitamin A esters (retinyl esters) in fish liver oils and its application in the detection of spurious drugs (Abstract)" by S. K. Chatterjee, N. K. Dey and R. Chanda, The Ind. J. of Pharmacy, Vol. 37, No. 6, p. 174 Nov/Dec. 1975.

4. "National Centre for Drug Reference Standards at the Central Drugs Laboratory, Calcutta" by Dr. P. C. Bose, Souvenir Vol. of the 14th National Pharmacy Week held in Calcutta, November, 1975.

5. "A new principle in analytical quality control of marketed drugs for Government regulatory purposes" by Dr. D. Ghosh, 35th International Congress of Pharmaceutical Sciences held in Dublin, Ireland, September, 1975.

6. "Method for detection and isolation of diethyleneglycol contamination in non-syrupy base of pharmaceutical formulations" by A. C. Das Gupta and others. The Eastern Pharmacist, Scientific Section, Vol. XIX, No. 223, July 1976.

1976-77

7. "Evaluation of Penicillin Eye Ointment for microbiological contamination" by M. K. Majumdar and others, Eastern Pharmacy.

8. "Analytical survey of Homoeopathic mother tincture for statutory quality control Part VIII; U.V. Absorption and TLC studies of mother tincture of Vasaka" by G. K. Munshi, V. Mudgal and R. Chanda, The Eastern Pharmacist, Vol. XX, No. 234, June 1977, pp. 89-90.

9. "TLC Estimation of some ingredients in Ayurvedic formulation drugs" by G. K. Munshi, V. Mudgal and R. Chanda, Jour. of Research in Indian Medicine/Yoga and Homoeopathy, Varanasi, (In Press).

10. "Antimicrobial activity of Trifala (*Terminalia belerica* Roxb. *Terminalia chebula* Retz. and *Phyllanthus emblica*, Linn) by P. G. Ray and R. Chanda, Jour. of Experimental Biology, CSIR., New Delhi.

11. "Vigilance on Quality of drugs" by R. Chanda, Your Health, Vol. 25, No. 297, September, 1976, p. 323.

12. "Colorimetric estimation of Ampicillin" by C. Chowdhury, The Ind J. of Pharmacy, Sept/Oct., 1976, Vol. 38, No. 5. 1976.

13. "A Note on the detection of related foreign steroids by B. P. Method" by V. K. Madan and S. C. Sharma, The Eastern Pharmacist, Scientific Section, Vol. XIX, No. 227, Nov. 1976, p. 73.

14. "Quantitative determination of buclosamide and salicylic acid in ointment preparation" by S. K. Chatterjee and S. C. Sharma, The Eastern Pharmacist, Scientific Section, Vol. XIX, No. 227, Nov. 1976, p. 71.

15. "TLC technique for detection of pharmaceutical drugs" by G. K. Munshi and S. K. Das, Indian Drugs and Pharmaceutical Industry, May/June 1976, Vol. XI, No. 3, p. 38.

16. "Estimation of Chloramphenicol palmitate and chloramphenicol in complex drug mixtures" by B. N. Sarkar, The Eastern Pharmacist, Scientific Ed., Vol. XIX, August, 1976, pp. 115-119.

17. "Detection of glycyrrhizic acid by TLC" by G. K. Munshi, Ind. Jour of Pharmacy, Vol. 38, No. 4, 1976, pp. 105-106.

18. "Screening of Homoeopathic mother tincture for antimicrobial activity" by P. G. Ray and S. K. Mukherjee, Ind. Jour. of Experimental Biology, CSIR, New Delhi (In Press).

19. "Identification of Corticosteroids by p. toluene sulphonic acid on thin layer chromatograms" by V. K. Madan and S. C. Sharma, Jour. of Institution of Chemists (India), Calcutta, Vol. XLIX, 1977, p. 61.

20. "Studies on the detection of optical brightener in absorbent cotton wool" by G. K. Munshi and R. Chanda, The Eastern Pharmacist, Vol. XX, No. 231, March 1977, pp. 97-98.

21. "Detection of Homoeopathic drugs from solid vehicles —I" by G. K. Munshi, V. Mudgal and R. Chanda, Jour. of the Institution of Chemists (India), Calcutta, XLVIII. 297 (1976).

22. "Thin Layer Chromatography of Six Yellow Coal Tar Dyes" by G. K. Munshi and S. K. Das, The Eastern Pharmacist, Vol XIX, No. 220, April 1976, p. 123.

23. "Identification of Indian Pharmacopoeial Crude Drugs by Thin Layer Chromatography Part I" by G. K. Munshi. The Eastern Pharmacist, Scientific Ed., Vol. XIX, No. 221, May 1976, p. 61.

24. "Vitamin requirements of antibiotics resistant intestinal lactobacilli" by P. R. Bhattacharya M. K. Majumdar and B. B. Ghosh, Ind. Jour. of Experimental Biology, 14 (1976), 508.

25. "Antimicrobial activity of some Indian Plants" by P. G. Ray and S. K. Majumdar, Economic Botany, 30, 1976, 317.

26. "Antifungal flavionoid from Alpinia Officinarum Hance" by P. G. Ray and S. K. Majumdar, Ind. Jour of Exp. Biol., 14, 1976, 712.

27. "Separation of Sorbitol Mannitol, Glucose and Fructose by hin Layer Chromatography" by G. K. Munshi and P. R. Bhattacharya, Jour. of the Institution of Chemists (India), Vol. XLIX March 1977 Part II, pp. 103-104.

28. "Physico chemical studies on cosmetic colours" by P. C. Bose, Souvenir, Silver Jubilee Celebration 1977, Forensic Science Laboratory, Govt. of West Bengal, Calcutta 37.

29. "Separation of acids of bacteria by thin layer chromatography" by P. Nath, M. K. Majumdar and B. B. Ghosh, Ind. Jour. of Physiology and Allied Sci. 29, (1975), 135.

30. "An antifungal compound from *Alpinia officinarum* Hance," by P. G. Ray and S. K. Majumdar, Ind. Jour of Exptl. Biol. 13, (1975), 409.

7.2 Research studies in progress include the following:—

1. Studies on certain aspects of physiology of antibiotics resistant intestinal Lactobacilli.

2. Synthesis of degradation/impurity standards for drug testing and toxicity studies.

3. Characterisation of Cosmetic Colours.

4. Determination of Panthenol in syrupy liquid preparations.

5. Effect of flavouring agents on the stability of Vitamin A

6. Study on the stability of pharmaceutical dosage forms of drugs particularly of Tranquilizers and antiprotozoal drugs including characterisation and synthesis of decomposition products.

7. Study of drug induced homolysi in evaluating drug toxicity.

8. REFERENCE STANDARDS

8.1 International Standards

The Central Drugs Laboratory, Calcutta, is the national Centre for collection, maintenance and distribution of International Standards for drugs and pharmaceuticals received from the World Health Organisation. The total number of such Standards available for distribution at the end of the period stood at 71. A total of 145 ampoules of different International Standards were distributed during the period.

During the year 1975-76 the work relating to the standardisation of C.D.L. Reference Substances with the corresponding International Chemical Reference Substances was started. During 1976-77, 11 new International Chemical Reference Substances were included in the List and the total number of such Substances stood at 74 at the end of the period. 84 of these Reference Substances were distributed during the three year period.

8.2 National Reference Standards (NRS)

Collaborative assay in respect of 2nd National Reference Standards for Penicillin G Potassium and Chloramphenicol have been completed and data forwarded to the Drugs Controller India, for approval. The following (14) National Reference Standards were available for distribution:—

(1) First NRS for Digitalis, (2) First NRS for Chloramphenicol, (3) First NRS for Streptomycin, (4) First NRS for Dihydrostreptomycin, (5) First NRS for Neomycin, (6) First NRS for Heparin Sodium, (7) First NRS for Oxytetracycline, (8) First NRS for Chlorteracycline; (9) 1st NRS for Folic Acid, (10) 1st NRS for Thiamine Hydrochloride, (11) 2nd NRS for Posterior Pituitary Lobe, (12) 2nd NRS for Insulin, (13) 2nd NRS for Tetracycline, (14) 1st NRS for Phenoxymethyl Penicillin Potassium.

A total of 406 ampoules of different National Reference Standards were distributed free of cost to Government Control Laboratories, Research Institutions, Pharmaceutical concerns, etc. during the period under report.

8.3 National Reference Standards for Vegetable Drugs

The following National Reference Standards (NRS) for vegetable drugs were available for distribution during the period:—

Crude Drugs	*Extracts*
1. Ashoka, I.P.	1. Ashoka Liq. Ext. I.P.
2. Kurchi, I.P.	2. Kurchi Liq. Ext. I.P.
3. Nux Vomica, I.P.	3. Vasaka Liq. Ext. I.P.
4. Podophyllum, I.P.	4. Nux Vomica Tincture, I.P.
5. Rauwolfia, I.P.	
6. Urginia, I.P.	
7. Vasaka, I.P.	
8. Cinchona, I.P.	

8.4 C.D.L. Reference Substances

The work relating to the collection, maintenance and preparation of Central Drugs Laboratory (CDL) Reference Substances of authentic specimens of antibiotics, vitamins, hormones, synthetic drugs, enzymes, biologicals, etc. continued during the period. The total number of CDL Reference substances stood at 331 at the end of the period. Altogether 705 CDL Reference Substances were distributed free of cost to drug manufacturers, State Drug Control Laboratories, Research Institutes, etc. for quality control purposes and research.

During the year 1974-75 a programme of work was initiated to standardise the CDL Reference Substances against corresponding B.P./U.S.P./N.R. Reference Standards. Such Reference materials will be used in place of corresponding foreign pharmacopoeial Standards to save foreign exchange and to do away with the difficulty of procuring these materials from abroad.

8.5 Indian Pharmacopoeial Reference Standards

All the 34 items of the Indian Pharmacopoeial Reference Standards are now available for distribution. During the year 1976-77 as many as 167 different I.P. Reference Standards were distributed to Drug Control Laboratories and other organisations.

8.6 Sub-Cultures of Micro-organisms required for analysis of drugs

Majority of cultures of micro-organisms which are required for drugs quality control purposes are maintained at the Central Drugs Laboratory and are distributed free of cost, when requested, to Government Drug Testing Laboratories, drug manufacturing firms, etc. A total of 127 different microbial cultures were distributed, free of charge, to different drug control laboratories, drug manufacturing firms, etc. during the period. At present 27 micro-organisms are maintained in this laboratory.

9. TRAINING OF DRUG ANALYSTS

Due to shortage of accommodation the scheme of Drug Analysts Training could not be fully implemented, though during the latter part of the years under report a large number of trainees, both from India and abroad took training in this Laboratory.

During 1974-75 two trainees from the Government of West Bengal and one each from Maharashtra and Kerala Governments took intensified training in instrumental and other methods of drug analysis. Another trainee from the Government Medical Store Depot Organisation also took training for about 2 months in pharmacological methods of drug analysis during this year.

During the year 1975-76 three trainees from the States of Karnataka, Haryana and Andhra Pradesh took training for about 2 months in this laboratory. Two World Health Organisation Fellows from Indonesia also took short training for about a week in January 1976 in this laboratory.

During 1976-77 under the scheme of intensified training in modern instrumental and other methods of drug analysis of short duration, 6 trainees got two months training in different Sections of this laboratory. Two trainees came from Karnataka State and one each from Maharashtra, Bihar, West Bengal and Central Indian Pharmacopoeia Laboratory, Ghaziabad, under the DGHS.

This laboratory is now recognised as a full fledged Training Centre by the World Health Organisation. In 1976-77 one WHO Fellow from Burma took about three months training in microbiological assay of Vitamins. Another WHO Fellow

from Afghanistan is getting detailed training in all Sections of this laboratory for a period of one year. A third WHO Fellow, also from Burma, is having thorough training in different aspects of drug analysis for a period of about 8 months.

10. INTENSIFIED DRUGS QUALITY CONTROL (IDQ) PROGRAMME

During the financial year 1974-75 no IDQ Programme could be undertaken, because the proposed programme on testing of Morphine and Pethidine samples could not be initiated due to difficulties of excise regulations.

During 1975-76 the IDQ Project No. 4 on Ampicillin capsules/tablets was undertaken. 794 samples of Ampicillin manufactured by 80 Firms and collected by the four Zones of the Central Drugs Standard Control Organisation were analysed within a very short time. Out of the 794 samples of Ampicillin examined, only 36 samples were found to be of sub-standard quality. But no spurious sample was detected amongst the sub-standard samples. This type of quick assessment of the quality status of Ampicillin, one of the latest antibiotics, manufactured within the country was of great help to the Drugs Standard Control Organisation at the Centre.

During 1976-77 two IDQ Projects No. 5 on Dexamethasone Tablets and Chloroquine Phosphate Tablets and No. 6 on all Chloramphenicol preparations (except Ointments) were undertaken. Under Project No. 5,603 samples of Dexamethasone tablets manufactured by 96 drug manufacturers and collected by the four Zonal offices of the Central Drugs Standard Control Organisation were analysed during a period of about 4½ months. Out of 603 samples examined, 552 samples were found to be of standard quality and 51 were sub-standard, including 2 spurious samples. 678 samples of Chloroquine Phosphate Tablets, manufactured by 164 Firms and collected from all the Zones of the C.D.S.C.O. were examined, out of which 657 samples were found standard and 21 samples sub-standard. No spurious sample was detected amongst such a large number of samples examined. Under IDQ Project No. 6 on all Chloramphenicol preparations (except Ointments) 1233 samples were received from the 4 Zones of the C.D.S.C.O. during a period of about 4½ months. Out of these 543 samples were tested, 510 samples were found to be of standard quality and 33 samples were found sub-standard and 6 samples were detected to be spurious.

This type of quick assessment of the quality of important and most extensively used drugs manufactured within the country offered a great help to the Drugs Standard Control Organisation at the Centre. The Project is now being modified to carry out National Surveys on the quality of essential drugs within the same category simultaneously.

11. INTERNATIONAL COLLABORATION

The Central Drugs Laboratory, Calcutta, continued to collaborate with the World Health Organization in matters regarding drugs quality control and standardisation problems.

During the latter part of the years under report, the Laboratory actively participated in the interantional collaborative assay of the proposed second international standard for Erythromycin replacement of international standard for Oxytocin, and the proposed international standard for Lysine Vasopressin, with National Institute for Biological Standards and Control, London.

Dr. R. Chanda, Director (Acting) has become a Member of the WHO Expert Advisory Panel on International Pharmacopoeia and Pharmaceutical Preparations.

12. EXPANSION PROGRAMME

Considerable expansion activities occurred at the Laboratory during the latter part of the period under report. During 1976-77, 3 new Divisions, e.g. Pharmaceutical Research, Reference Standards and Toxicology have been created to meet the increasing needs of developmental programme under the Fifth Five Year Plan. Thirteen new posts have been created for this purpose, of which ten were filled up, including 3 posts of Senior Scientific Officers Class I. In addition, several posts which lapsed as a result of their remaining vacant for more than 6 months, have been revived and filled up. During 1976-77, nearly 4000 drug samples were tested and further acceleration of testing is being planned so as to reach the target of 7500 samples per annum by the end of the Fifth Five Year Plan in 1978-79.

All the superstructure of the new multi-storeyed building for the Central Drugs Laboratory is now complete and it is expected that the Laboratory would be able to move to the new building early 1978.

2—25 DGHS/ND/78

Several other new research projects have been initiated as already mentioned under item No. 7.2 in page 12 before. Two of these research projects have been accepted for the first time, by the Universities of Calcutta and Jadavpur for higher degrees.

In October 1976 a Conference of State Government Analysts was held in this Laboratory, after a lapse of nearly 12 years, under the chairmanship of Drugs Controller (India). Dr. R. Chanda, acting Director was the Convenor of the Conference. Dr. Chanda was also elected as the Convenor of the Working Group on Standards for Patent and Proprietary Preparations during this Conference. In pursuance of the recommendations made at this Conference three other Working Groups or Sub-Committees were also formed on:

(i) Working Group to draw up Specifications for Particulate matters in parenteral preparations;

(ii) Sub-committee on Cosmetic Colours and Standards for Cosmetics;

(iii) Sub-committee on Work Norms for Analysts with Officers this Laboratory as Members.

13. MEMBERSHIP OF SCIENTIFIC AND STATUTORY COMMITTEES

The Director (Actg), Central Drugs Laboratory is a Member of the following Statutory and Scientific Committees:—

(a) Indian Standards Institution Committees and Panels.

(b) Chartered Chemist and Fellow, Royal Institute of Chemistry, London.

(c) Indian Science Congress Association.

(d) Institution of Chemists (India).

(e) Associate Editor, Journal of Institution of Chemists (India).

(f) Biochemical Society and the Nutrition Society (London).

(g) Drugs Technical Advisory Board.

(h) Pharmacy Council of India.

(i) Drug Consultative Committee.

(j) Homoeopathic Pharmacopoeia Committee of India.

(k) Unani and Ayurvedic Drugs Technical Advisory Board.

(l) State Advisory Committee on Drugs of the Govt. of West Bengal.

(m) Hony. Secretary, The Royal Institute of Chemistry and the Chemical Society, Eastern India Section.

Several other officers of this Laboratory are Members of the Indian Standards Institution Sub-Committees and Panels.

14. VISITORS

During 1974-75 *the following amongst others visited the Central Drugs Laboratory, Calcutta*:—

(1) Hon'ble Dr. Karan Singh, Minister of Health and F.P., Government of India.

(2) Shri A. K. M. Ishaque, Deputy Minister of Health & F.P., Government of India.

(3) Members of the Hathi Committee on Drugs and Pharmaceuticals Industry headed by the Chairman, Shri Jaisukhlal Hathi, M.P.

(4) Dr. Habibuz Zaman, Regional Medical Officer (Fellowships), World Health Organization, Regional Office for South East Asia, New Delhi.

During 1975-76 *the following amongst other visited this Laboratory*:—

(5) Shri Shravan Kumar, Joint Secretary, Ministry of Health and F.P., Government of India.

(6) Dr. Ko Ko, Assistant Director of Health Services, WHO Regional Office for South East Asia, New Delhi.

(7) Dr. S. S. Gothoskar, Drugs Controller (India), Govt. of India.

(8) Shri R. B. Pany, Drugs Controller, Orissa, Bhubaneshwar.

(9) Shri T. R. Baggi, Asstt. Director, Central Forensic Science Laboratory, Hyderabad.

During 1976-77 *the following visited the Central Drugs Laboratory*: —

(10) A group of about 12 Final B. Pharm. students of the Government College of Pharmacy, Bangalore.

(11) Prof. P. N. Mehra and other Members of the Homoeopathic Pharmacopoeia Committee.

(12) Shri R. N. Sinha, Director of Administration, D.G.H.S., New Delhi.

(13) Shri J. S. Bali, Additional Secretary, Ministry of Health & FP.

(14) Six students of the post-graduate class of the Deptt. of Botany, University College of Science, Calcutta University, accompanied by their Teacher.

(15) Shri M. R. Kerudi, Superintendent, Drug Testing Laboratory, Govt. of Karnataka, Bangalore.

The following also visited the Central Drugs Laboratory during or after the conclusion of the Govt. Analysts Conference in October, 1976: —

(16) Dr. S. S. Gothoskar, Drugs Controller (India).

(17) Dr. P. R. Pabrai, Director, Central Indian Pharmacopoeia Laboratory, Ghaziabad.

(18) Shri R. G. Tamhane, Asstt. Director, Drug Control Laboratory, Maharashtra State, Bombay.

(19) Shri B. C. Mehta, Senior Scientific Officer, Drugs Control Laboratory, Bombay.

(20) Shri A. D. Nadkarni, Senior Scientific Officer, Drugs Control Laboratory, Bombay.

(21) Mrs. Kamalesh Jain, Govt. Analyst, Haryana, Chandigarh.

(22) Dr. A. C. Kar, Director, Drugs Control, West Bengal Govt.

(23) Dr. M. A. Patel, Joint Director, Drugs Laboratory, Baroda.

APPENDIX I

Statement of samples received from various sources and tested in the Central Drugs Laboratory, Calcutta during the financial year 1974-75.

	Samples received from				*Total*		
	Drugs Inspectors	Drugs Controller, India, Central Drug Standard Control Organisation & Miscellaneous	Customs	Law Courts	Received	Tested	Standard
No. of samples received.	717	303	537	3	1560	..	..
No. of samples tested	926	403	528	4	..	1861	..
No. of samples found standard.	507	243	464	2	..	..	1216

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APPENDIX I—*Contd.*

Statement of samples received from various sources and tested in the Central Drugs Laboratory, Calcutta during the financial year 1975-76.

	Samples received from				*Total*		
	Drugs Inspectors	Drugs Controller, India, Central Drug Standard Control Organisation & Miscellaneous	Customs	Law Courts	Received	Tested	Standard
No. of samples received.	413	473	689	10	1585	..	..
No. of samples tested.	512	475	676	4	..	1667	..
No. of samples found standard.	275	303	558	1	..	..	1137

APPENDIX I—*Concld.*

Statement of samples received from various sources and tested in the Central Drugs Laboratory, Calcutta during the financial year 1976-77.

	Samples recived from				*Total*		
	Drugs Inspectors	Drugs Controller, India, Central Drug Standard Control Organisation & Miscellaneous	Customs	Law Courts	Received	Tested	Standard
No. of samples received.	1005	1140	447	27	2619	..	..
No. of samples tested.	721	917	458	10	..	2106	..
No. of samples found standard.	405	580	407	3	..	..	1395

APPENDIX 2

Pharmaceutical Chemistry Department—List of Imported Drug Samples Found Sub-Standard in the year 1974-75.

Names of Drugs	No. Tested	No. Sub-standard	Reasons for Rejection
	Pharmacopoeial		
Ampicillin Sodium	4	1	Loss on drying
Chloroquine Phosphate	10	1	pH fails
Clofibrate	10	1	Free acidity and free Phenolic bodies.
Citric Acid	5	1	Tartaric acid and readily carbonisable substances above limit.
Chloramphenicol Palmitate oral Supn.	1	1	Polymorph A limit high
Doxycycline Hydrochloride	4	1	Sulphated ash limit high
Ergometrine Tartrate	5	1	Assay low
Guaiacol Glycery Ether	3	2	Guaiacol limit fails
Magnesium Oxide	5	2	High Heavy metals, chloride
Metronidazole	33	2	Melting point, Assay
Oxyphenbutazone	43	35	Clarity and colour of solution
Povidone	6	2	Loss on drying
Pectin	4	1	Assay low
Quinine Sulphate	1	1	Inorganic salts and other
Sulphamethoxypyridazine	6	1	Identification negative
Sulphamethoxazole	9	1	Identification negative
TOTAL	149	54	
	Non-Pharmacopoeial		
Adrenochrome Monosemi Carbazone	2	1	Assay low
Amino Caproic Acid	1	1	Assay low
Arsenic Trioxide	1	1	Solubility, Arsenious Sulphide limit
Cetosteryl alcohol	2	1	Melting point
Quinic acid	1	1	Melting point
TOTAL	7	5	

APPENDIX 2—*Contd.*

Pharmaceutical Chemistry Department—List of State Drug Samples Found Sub-Standard in the year 1974-75.

Names of Drugs	No. tested	No. Sub-standard	Reasons for Rejection
Pharmacopoeial			
Acriflavine	1	1	Identification negative
Acetyl salicylic Acid tab	9	4	Free Salicylic acid limit
Acetyl salicylic Acid Comp tab	1	1	Free salicylic acid limit
Ampicillin Cap	5	2	Assay, Disintegration
Analgin tab	9	1	Description
Analgin Injection	4	1	Suspended impurities
Atropine Sulph Injection	11	5	pH, assay, Suspended impurities.
Calcium Gluconate Inj.	3	3	Suspended particles, assay
Calcium P.A.S. Granules	1	1	Disintegration
Chlor. Palm. Oral Suspension	22	5	Polymorph A limit, assay
Chloramphenicol Cap	56	8	Spurious, Disintegration, Assay
Chloroquine Phos Tab	6	1	Assay low, Disintegration
Chloroquine Phos Inj.	8	4	Suspended particles
Chlordiazepoxide HCl	1	1	Decomposition products above limit.
Chloral Hydrate	1	1	Reaction
Clofibrate	4	2	Free acidity and free phenol limit high.
Codeine tab	2	1	Assay low
Cyanocobalamin Inj.	6	2	Suspended particles pH high
Dextrose Inj.	86	51	Phenol present, Suspended particles.
Dextrose & Sodi Chloride Inj.	56	37	Phenol present, suspended particles.
Disinfectant fluid	2	2	Coal tar acid content low
Ferrous Sulph tab	3	2	Assay fails.
TOTAL	297	136	

APPENDIX 2—*Contd.*

Pharmaceutical Chemistry Department — List of State Drug Samples Found Sub-Standard in the year 1974-75.

Names of Drugs	No. tested	No. sub-standard	Reasons for Rejection
	Pharmacopoeial		
	297	136	
Fortified penicillin & Strep Inj.	44	5	Assay low, Description, pH
Glycerine	8	6	Spurious, wt. per ml. Reducing Sugar.
Morphine Inj.	4	1	pH
No-Adrenalin Acid tartrater	1	1	pH
Olive oil	2	1	Assay low
Oxytetracycline Cap	7	3	Description, Disintegration, Assay.
Oxytetracycline Inj.	21	6	pH Suspended particles
Paraldehyde	2	2	Boiling range, Acidity
Penicillin lozenges	2	2	Description
Pethidine Inj.	11	2	Spurious
Phenylbutazone	1	1	Clarity and colour of solution
Phenylbutazone tab	2	1	Disintegration, Description
Phenobarbitone tab	1	1	Disintegration
Piperazine Citratec Syrup	1	1	Assay low
Povidone Inj.	1	1	Suspended particles
Promethazine HCl tab	1	1	Disintegration, Description
Sodium Chloride Inj.	22	14	Suspended particles
Sodium Lactate Inj.	6	3	Suspended particles
Sodium Chloride	11	3	Solubility, Loss on drying
Sodium bi-carbonate	7	3	Reaction
Sodium bi-carbonate Inj.	1	1	Suspended particles
Sulphacetamide Eye Drops	5	3	Description
TOTAL	458	198	

APPENDIX 2—*Contd.*

Pharmaceutical Chemistry Department—List of State Drug Samples Found Sub-Standard during the year 1974-75.

Names of Drugs	No. tested	No. sub-standard	Reasons for Rejection
Pharmacopoeial			
	458	198	
Sulphanilamide tab	4	2	Disintegration
Sulphadiazine tab	9	2	Identification negative wt. varied.
Tetracylicne HCl cap	28	8	Spurious, Description, Disintegration.
Tetracycline Inj.	3	1	pH, Suspended particles
Trisulphonamide tab	1	1	Assay low, Disintegration
Turpentine Liniment	5	2	Description
Water for Inj.	11	3	Suspended particles oxidisatable matter.
TOTAL	519	217	
Non-Pharmacopoeial			
Alergin Syrup	1	1	Assay of Chlorpheniramine Maleate low.
Alkatron	1	1	Fungus
Alfa Cough Syrup	1	1	Assay low
Chloramphenicol + Streptomycin Cap.	10	1	Spurious
Chloroquin Phosphate Inj.	2	2	Suspended impurities
Calcipirin tab	1	1	Salicylic acid limit high
Chromostat Inj.	3	1	Assay low
Cassia Pain Balm	1	1	Assay low
Cypen-Strep Cap	1	1	Decomposed
Duemycin	1	1	Assay low
Diquill Inj.	1	1	Suspended particles
Gripe Water	6	5	Suspended particles. Assay low
Intesep	1	1	Decomposed
Irgapyrin Inj.	1	1	Suspended particles
Influenza tab	1	1	Assay low
Lipecems	1	1	Description
Parcular Eye drop	1	1	pH high, Description
Phenylbutazone + Amidopyrin Inj.	2	1	Suspended particles, Assay low
Penidune LD 24	1	1	Description
Primidon tab	2	1	Disintegration
Uripyne	1	1	Assay low
TOTAL	40	26	

APPENDIX 2—*Contd.*

Pharmaceutical Chemistry Department—List of Court Case Samples Found Sub-Standard during the year 1974-75.

Names of Drugs	No. tested	No. sub-standard	Reasons for Rejection
Suspected to be Black Disinfectant fluid.	1	1	Identification negative

APPENDIX 2—*Contd.*

Pharmaceutical Chemistry Department—List of Imported Drug Samples Found Sub-Standard during the year 1975-76.

Names of Drugs	No. tested	No. sub-standard	Reasons for Rejection
	Pharmacopoeial		
Ampicillin Sodium . . .	2	1	Water limit high
Calcium Hypophosphite .	1	1	Acidity limit high
Camphor . . .	1	1	Melting range & Non-volatile matter.
Chloramphenicol . . .	2	1	Melting range and light absorption.
Chlorpromazine tab . . .	1	1	Description
Chloroquine Phosphate .	35	15	Loss on drying, Description
Cinnamon oil . . .	1	1	Solubility & optical rotation
Clofibrate . . .	4	1	Free phenolic bodies high
Clove oil	4	2	Phenol limit high, Assay low
Cocaine HCl . . .	1	1	Identity negative (Found to be KCl).
Cyclophosphamide . . .	2	1	Identity & chloride
Cycloserine . . .	2	2	Condensation product limit high.
Ephedrine HCl . . .	12	2	Identified as reacemic variety
Framycetin Sulph . . .	3	1	Water limit high
Metronidazole . . .	21	1	Identification negative
Neomycin Sulphate . . .	4	1	Loss on drying high
Oxyphenbutazone . . .	108	29	Colour & clarity of solution and Residue on ignition.
Paraldehyde . . .	3	1	Solubility & Amyl alcohol limit.
Pectin	8	3	Starch, Ash, Assay, organic acid.
TOTAL .	215	66	

APPENDIX 2—*Contd.*

Pharmaceutical Chemistry Department—List of Imported Drug Samples Found Sub-Standard during the year 1975-76.

Names of Drugs	No. tested	No. sub-standard	Reasons for Rejection
Pharmacopoeial			
	215	66	
Phenytoin Sodium	8	3	Solubility and loss on drying
Phenylbutazone . . .	14	6	Colour and clarity of solution
Phenformin HCl . . .	4	1	Melting point and Assay
Pippermint oil . . .	2	1	Identity, Ref. Index, Solubility in alcohol, wt. per ml.
Povidone . . .	7	2	Relative viscosity, Moisture
Sodium Benzoate . . .	2	1	Identity negative
Sorbitol	11	3	Reducing sugar, Description sp. gravity. Ref. Index.
Sulphamethoxypyradazine .	2	1	Identification negative
TOTAL .	269	85	
Non-Pharmacopoeial			
Calcium Lactobionate . .	1	1	Chloride + loss on drying limit high.
Epsilon Amino Capric Acid .	1	1	Stability test fails
Melleril Substance . .	1	1	Solubility & Assay low
Pyrithyldione . . .	2	2	Loss on drying, Melting point
Quinic Acid . . .	1	1	Melting point.
	6	6	

APPENDIX 2—*Contd.*

Pharmaceutical Chemistry Department—List of State Drug Samples Found Sub-Standard during 1975-76.

Names of Drugs	No. tested	No. sub-standard	Reasons for Rejection
	Pharmacopoeial		
Absolute Alcohol	1	1	Fusal oil constituents limit
Acetyl Salicylic Acid	2	1	Salicylic Acid limit
Aluminium Hydroxide tab	2	1	Acid consuming capacity
Aminophyllin Inj.	2	1	Suspended impurities
Ampicillin Capsule	10	6	Assay low, Disintegration for tab.
Analgin Inj.	4	2	Suspended impurities, Brown liquid.
A.P.C. tab.	4	2	Spurious, Description
Atropine Sulphate Inj.	4	1	pH fails.
Boric Acid	1	1	Sulphate limit high
Calcium P.A.S. Granules	1	1	3-aminophenol limit high
Chloramphenicol Palmitate oral Suspension.	8	2	Assay low
Clofibrate Cap.	3	3	Free acidity limit, Free phenolic bodies.
Calcium gluconate Inj.	3	3	Suspended impurities
Comp. Sodi lactate Inj.	1	1	Suspended impurities
Dextrose Inj.	1	1	Suspended impurities
Dextrose & Sodi chloride Inj.	1	1	Suspended impurities
Ergot tab	1	1	Disintegration
Ferrous Sulph tab	2	1	Description of the tablet
Glycodin	6	6	Adulterated with reducing sugar spurious
Lignnocain + Adrenalne Inj.	1	1	Suspended Impurities, pH limit Assay.
Liniment Turpentine	3	1	Separated into layers
TOTAL	61	38	

APPENDIX 2—*Contd.*

Pharmaceutical Chemistry Department—List of State Drug Samples Found Sub-Standard during 1975-76.

Names of Drugs	No. tested	No. sub-standard	Reasons for Rejection
	Pharmacopoeial		
	61	38	
Normal Saline Inj.	1	1	Suspended impurities
Oxytetracycline Inj.	7	1	Suspended impurities
Oxyphenbutazone tab.	2	1	Assay low.
Paracetamol Inj.	2	1	Suspended impurities
Phenylbutazone	1	1	Colour and clarity of solution
Pheniramine Maleate Inj.	1	1	Does not contain Sodium chloride as claimed.
Silver proteinate	1	1	Description
Sodium Antimony Gluconate Inj.	7	5	Spurious, Acidity high, Iron as impurity.
Sodium bicarbonate	1	1	pH limit, chloride limit, Assay.
Sulphadimidin tab	10	2	Uniformity of wt. of tab. Assay
Sulphanilamide tab	2	2	Identified as Sulphadimidine
Sulphadiazine tab	1	1	Disintegration test fails
Trifluopromaxine Inj.	2	1	Suspended impurities. Assay low.
Zinc Oxide Ointment.	2	2	Assay low
	101	59	
	Non-Pharmacopoeial		
Amrutanjan Pain Balm	3	1	Claimed as Ayurvedic but contains methyl Salicylate.
Ananda Kar (Aspirin, Paracetamol + caffeine).	1	1	Salicylic acid limit high
Alkatron	1	1	Assay low.
Azo, Antacid tab	1	1	Does not contain Phenobarbitone one of the constituents
Bromdol	1	1	Melting point high
Chlor palmitate oral suspn. C Vitamin.	1	1	Assay of Antibiotic low
Chlor. palm. oral suspn. C Streptomycin	1	1	Polymorph A content high
Calcispirin	1	1	Salicylic Acid limit high
	10	8	

APPENDIX 2—*Contd.*

Pharmaceutical Chemistry Department—List of State Drug Samples Found Sub-Standard during 1975-76

Names of Drugs	No. Tested	No. Sub-Standard	Reasons for Rejection
Non-Pharmacopoeial			
	10	8	
Digin Gel . . .	1	1	Description
Endoxan Asta (Chlorpropomide Ins.)	1	1	Description. Water content.
Gripe water . . .	12	1	Suspended impurities, No Sodium bi-carbonate.
Intestrep (Chloroquine Phos & Halquinol tab).	1	1	Fungus on the tab.
Panjon tab (Aspirin, Caffeine, paracetamol).	1	1	Aspirin content low
Paracetamol Inj. . . .	1	1	Description
Pain Balm asika . . .	1	1	Does not contain Methyl Salicylate.
Siozide Syrup . . .	2	1	Suspended impurities
Triphen tab . . .	1	1	Description
Unienzyme tab . . .	1	1	Description
TOTAL .	32	18	

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APPENDIX 2—*Contd.*

Pharmaceutical Chemistry Department — List of Court Case Samples Found Sub-Standard during 1975-76

Names of Drugs	No. Tested	No. Sub-Standard	Reasons for Rejection
Aspirin tab . . .	1	1	Description, Uniformity of wt. Salicylic Acid limit, assay
Morphin & Pethedin Inj. . .	1	1	Sample does not contain morphine pethidine
Phenylbutazone	1	1	Sample does not contain Phenylbutazone
Piperazine Citrate . . .	1	1	Assay low
Star Castor oil . . .	3	3	Acid value high
TOTAL .	7	7	

APPENDIX 2—*Contd.*

Pharmaceutical Chemistry Section—List of Improved Drug Samples Found Sub-Standard during 1976-77

Names of Drugs	No. Tested	No. Sub-Standard	Reasons for Rejection
	Pharmacopoeial		
A.P.C. Tabs	2	2	Salicylic Acid limit high
p-Amino Caproic Acid	1	1	Solubility fails
Chloroquin Phosphate	2	1	Loss on drying high
Cetrimide	4	1	Identification negative
Clove oil.	1	1	Assay low
Cycloserine	2	2	Description, Condensation products
Cellulose Acetate Phthalate	1	1	Loss on drying fails
Doxycycline HCl	24	4	Sulphated ásh high
Dextropropoxyphen HCl	6	1	Identification negative
Imipramine HCl	3	1	Appearance of solution, Loss on drying
Methyl parahydroxybenzoate Sodium	1	1	Solubility, Alkalinity
Neomycin Sulphate	4	1	Loss on drying
Oxypheabutazone	33	6	Clarity and colour of solution
Povidone	1	1	Loss on drying
Phenformin HCl	1	1	Melting point low
Pectin	3	1	Assay low
Refampicin	7	1	Identification negative
Sorbitol 70%	17	3	Reducing sugar limit high, Description
Sulphamethoxypyradazine	12	3	Identification negative
Tetracycline Phosphate Complex	7	6	Tetracycline base limit high, Solubility Moisture, Absorptivity
	132	39	
	Non-Pharmacopoeial		
Calcium Lactobionate	2	2	Melting point, Loss on drying Sp. rotation
Hydroxyethyl theophylline	3	1	Purity test fails
Polyvinyl Pyrrolidone (Inj Grade)	4	2	Viscosity fails
	9	5	

APPENDIX 2—*Contd.*

Pharmaceutical Chemistry Department—List of Court Case Samples Found Sub-Standard during 1976-77

Names of Drugs	No. Tested	No. Sub-Standard	Reasons for Rejection
Acetyl Salicylic acid tab	2	1	Description, Uniformity of wt. Limit for Salicylic Acid, assay
A.P.C. Co. tab	1	1	Limit for Salicylic acid, Assay
Chloroquin Phosphate Inj.	2	1	Suspended particles
Diphenhydramin Syrup	1	1	Description, assay
Mag Sulph	1	1	Description, Solubility
Sulphuric Acid Dil.	1	1	Ash content high
	8	6	

APPENDIX 2—*Contd.*

Pharmaceutical Chemistry Department—List of State Drug Samples Found Sub-Standard during the year 1976-77

Names of drugs	No. Tested	No. Sub-Standard	Reasons for Rejection
Pharmacopoeial			
Acetyl Salicyclic Acid Tab	5	3	Disintegration test, Free Salicylic acid limit
A.P.C. Tab	31	9	Free Salicyclic acid limit, Spurious-5, Misbranded
Adrenalin lignocaine Inj.	1	1	Suspended impurities
Alcohol	1	1	Fusel oil constituents high.
Aminophyllin Injection	3	1	Suspended impurities
Ampicillin Capsule	13	6	Uniformity of wt., Disintegration Assay low
Ampicillin Mixture	6	3	Ampicillin content low, Spurious
Chalmoograh oil	2	1	Description, sap. value, Sp. rotation
Chloroquin Phosphate Inj.	16	12	Suspended impurities
Chloroquin Phos Tab	27	3	Spurious
Chloramphenicol Capsule	10	3	Spurious, uniformity of wt.
Codeine Phos Syrup	1	1	Assay low
Diiodohydroxyquinoline tab	3	1	Disintegration
Glycerine	10	7	Spurious, Description, wt. per ml, colour
Isoniazid tab	5	5	Diameter of tab
Lignocaine Inj.	10	4	Suspended impurities, pH
Mag. Trisilicate	3	1	Chloride limit high
Mag. Trisilicate Comp. tab	3	1	Diameter
Morphine Inj.	4	1	pH.
Niketharnide Inj.	2	1	Acidity or alkalinity
Nitrofurantoin tab	5	1	Diameter, Assay
Paraffin liquid	3	2	Wt. per ml, Viscosity
TOTAL	164	68	

APPENDIX 2—*Contd.*

Pharmaceutical Chemistry Department—List of State Drug Samples Found Sub-Standard during the year 1976-77

Names of drugs	No. Tested	No. Sub-Standard	Reasons for Rejection
	Pharmacopoeial		
Paraldehyde	1	1	Solubility, Chloride, Amyl alcohol
Potassium Chloride	1	1	Description, Calcium and Magnesium Bromide & Iodide
Potassium Iodide	1	1	Description Loss on drying
Silver proteinate	1	1	Description
Sodium Amino Salicylate Tab	1	1	Description
Sodium bicarbonate Comp tab	1	1	Uniformity of wt.
Sodium Stibogluconate Inj.	6	1	Suspended impurities
Succinyl chloine chloride Inj.	2	2	Hydrolysis product limit high
Sulphadiazine tab	14	1	Spurious
Sulphadimidine tab	11	3	Spurious. Description
Sulphaguanidine tab	22	3	Spurious, Description. Assay
Sulphanilamide tab	2	1	Disintegration
Sulphamethaxazole Trimethoprim tab	1	1	Diameter
Tetracycline Cap	15	3	Spurious, Assay
Water for Inj.	1	1	Oxidisable matter
Zinc Oxide	2	1	Lead-limit high
TOTAL	246	91	

APPENDIX 2—*Concld.*

Pharmaceutical Chemistry Department—List of State Drug Samples Found Sub-Standard during 1976-77

Names of drugs	No. Tested	No. Sub-Standard	Reasons for Rejection
Non-Pharmacopoeial			
Bronidiol	1	1	Melting point low
Adrenochrom mono semi Carbozon Inj.	2	2	Suspended impurities, Volume low
Analgesic+antipyratic tab	10	7	Salicyclic acid limit high, Disintegration Assay
Analgin Inj.	5	2	Suspended impurities
Antacid tab.	23	2	Assay low
Aspirin+Prednisolone tab	1	1	Free Salicyclic acid limit high
Chloramphenicol + Streptomycin Suspension	1	1	Assay low
Chloramphenicol + Nitrofurantoin Suspension	1	1	Description, Identification
Chloroquin, Phthalylsulphathiazole and Quiniodochlor tab	1	1	Disintegration fails
Disodium Hydrogen Citrate	1	1	Assay low
Gripe Mixture	2	2	Suspended impurities
Hydroxethyltheophyllin, Paparain & Phenobarbiton tab	2	1	Disintegration
Iodine ointment	2	2	Iodine content low
Lacto-Calamine	1	1	Residue, Phenol
Olive oil+Arachis oil mixture	2	1	Iodine value low
Phthalylsulphacetamide and Diiodohydroxyquinolin	1	1	Description
Trifluprazine HCl Inj.	1	1	Suspended impurities
Xylotox Inj.	1	1	Total chloride high
TOTAL	58	29	

APPENDIX 3

Biochemistry Department—List of Imported Drug Samples Tested during the year 1974-75

Names of Drugs	No. Tested	No. Sub-Standard	Reasons for Rejection
Pharmacopoeial Drugs			
Ascorbic acid	5	..	
Calcium pantothenate	2	..	
Choline bitartarate	1	1	High moisture content
Choline Chloride	1	..	
Choline dihydrogen citrate	3	..	
Choline theophyllinate	2	..	
Dehydrocholic acid	1	..	
Dexamethasone	5	..	
Dexamethasone 21-Sodium Metasulfobenzoate	1	..	
Diastase malt	2	2	Low diastase activity failed in description
Ethisterone	1	..	
Glutamic acid	1	..	
Inositol	2		
Lynoestrenol	1	..	
Lysine monohydrochloride	6	..	
Methandienone	1	..	
DL Methionine	1	..	
Nandrolone phenyl propionate	3	..	
Nicotinamide	5	..	
Norethisterone	2	..	
Norethisterone acetate	2	..	
Pancreatin	5	2	Low amylase activity
DL Panthenol	1	..	
Pepsin	7	..	
Prednisolone	2	..	
Pyridoxine hydrochloride	2	..	
Rutin	4	..	
Triamcinolone	1	..	
Triamcinolone acetonide	1	..	
Vitamin E	5	..	
TOTAL	76	5	

APPENDIX 3— *Contd.*

Biochemistry Department—List of Imported Drug Samples Found Sub-Standard during 1974-75

Names of Drugs	No. Tested	No. Sub-Standard	Reasons for Rejection
Non-Pharmacopoeial			
	76	5	
DL Acetyl methionine . .	1	..	
Betaine base	1	..	
D Biotin	1	..	
Casein	1	..	
Multivim pediatric drops . .	1	1	Failed in Vitamin C content
Omnadin	1	..	
Tricholine citrate . . .	2	1	Failed in chloride limit test
TOTAL	8	2	

APPENDIX 3—*Contd.*

Biochemistry Department—List of State Drug Samples Tested during the year 1974-75.

Names of Drugs	No. Tested	No. Sub-Standard	Reasons for Rejection
Pharmacopoeial			
Ascorbic acid tablets	6	..	
Betamethasone tablets	2	..	
Dexamethasone tablets	21	..	
Dexamethasone	1	..	
Dexamethasone Sodium phosphate injection	7	..	
Hydroxy progesterone injection	4	2	Spurious
Insulin injections	2	..	
Insulin Zinc Suspension injection	1	..	
Liver injection crude	14	..	
Nandrolone phenyl propionate injection	3	1	Spurious
Nicotinamide	1	..	
Prednisolone tablets	24	6	
Riboflavine tablets	2	..	
Shark Liver oil (Dilute)	1	1	Failed in identification
Thiamine hydrochloride injection	14	3	Contained suspended particles
Vitamin A capsules	1	..	
Vitamin ABD Capsules	2	2	Failed in Vitamin A content
Yeast tablets	1	..	
TOTAL	107	15	

APPENDIX 3—*Contd.*

Biochemistry Department—List of State Drug Samples Tested during the year 1974-75

Names of Drugs	No. Tested	No. Sub-Standard	Reasons for Rejection
	Non-Pharmacopoeial		
B Complex capsules	1	..	
B Complex injection	50	34	Contained suspended particles
B Complex injection with other drugs	5	..	
B Complex Syrup	19	..	
B Complex Syrup with enzymes	19	12	Failed in respect of diastase, Papain and pepsin activity
B Complex Syrup with other drugs	34	3	Low B_1 content; Failed in description
B Complex tablets	18	..	
B Complex tablets with enzymes.	3	1	Failed in diastase activity
B Complex tablets with other drugs	8	..	
Colloidal Calcium with Vitamin D_2 and B_{12} (Injection)	10	8	Failed in D_2 content
Enzyme oral liquid preparations	5	4	Failed in respect of diastase and papain activity
Liver extract with other drugs (Injection)	2	..	
Multivitamin capsules	1	1	Folic acid absent
Multivitamin capsules with other drugs	3	..	
Multivitamin injection	1	..	
Multivitamin injection with other drugs	1	..	
Multivitamin Syrup	14	3	Failed in ascorbic acid and vitamin A content; contained precipitated matter
Multivitamin Syrup with other drugs	16	7	Failed in respect of Vitamin A content; contained precipitated matter
Multivitamin tablets	19	5	Failed in Vitamin C content
Steroid tablets with other drugs	6	1	Low prednisolone content
Vitamin C capsules with antibiotics	3	1	Low Vitamin C content
Miscellaneous Injections	2	..	
Ear/Eye drops	1	..	
Oral liquid preparations	8	..	
Ointments	2	..	
Tablets/powder	4	1	Failed in diastase activity
TOTAL	255	81	

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APPENDIX 3—*Contd.*

Biochemistry Department—List of Imported Drug Samples Tested during the year 1975-76

Names of Drugs	No. Tested	No. Sub-Standard	Reasons for Rejections
	Pharmacopoeial		
Ascorbic acid	2	..	
Choline Chloride	1	..	
Choline dihydrogen citrate	2	..	
Cyanocobalamin	1	..	
Cyanocobalamin injection	1	..	
Dexamethasone	7	..	
Dexamethasone acetate	1	..	
Fluocortolone caproate	2	..	
Inositol	4	..	
Lynoestrenol	1	..	
Lysine monohydrochloride	5	..	
Menadione Sodium bisulphite	1	..	
Methandienone	1	..	
DL Methionine	2	..	
Nandrolone phenyl propionate	2	..	
Nicotinamide	7	..	
Norethisterone acetate	1	..	
Norgestrel	2	..	
Pancreatin	6	1	Low trypsin and amylase activity
Pepsin	8	..	
Prednisolone	13	9	High moisture content; Mixture of prednisolone with some other unidentified ingredient
Pyridoxine hydrochloride	5	1	Failed in description and loss on drying
Riboflavine	1	..	
Rutin	3	..	
Thiamine hydrochloride	32	8	Samples were found to be thiamine mononitrate/Phenacetin. One sample could not be identified
Thiamine mononitrate	4	1	Sample found to be thiamine hydrochloride
Vitamin E	1	..	
TOTAL	117	20	

APPENDIX 3—*Contd.*

Biochemistry Department—List of Imported Drug Samples Tested during the year 1975-76

Names of Drugs	No. Tested	No. Sub-Standard	Reasons for Rejection
Non-Pharmacopoeial			
Allyl estrenol	1	..	
Citrus bioflavonoid compound .	1	..	
Delta-1 testolactone . . .	1	..	
Ethyl estrenol . . .	1	..	
Hypophosphito ascorbate calcium	1	..	
Nicofuranose	1	..	
Omnadin	1	..	
Tricholine citrate . . .	2	..	
TOTAL	9	..	

APPENDIX 3—*Contd.*

Biochemistry Department—List of State Drug Samples Tested during the year 1975-76

Names of Drugs	No. Tested	No. Sub-Standard	Reasons for Rejection
Pharmacopoeial			
Ascorbic acid tablets	9	3	Low vitamin C content and failed in description
Betamethasone sodium phosphate injection	2	..	
Betamethasone tablets	1	..	
Calcium pantothenate tablets	1	..	
Cyanocobalamin injection	5	2	Failed in respect of pH and cyanocobalamin content; contained suspended particles
Dexamethasone tablets	11	1	Failed in weight variation
Dexamethasone sodium phosphate injection	1	1	
Diethylstilboestrol tablets	1	1	Low diethylstilboesterol content
Folic acid tablets	1	..	
Heparin injection	2	..	
Insulin injection	3	..	
Liver injection	6	3	Failed in respect of total solid
Menadione sodium bisulphite injection	1	..	
Nicotinamide	1	..	
Prednisolone tablets	22	5	Spurious, tablets contained filthy materials, prednisone found instead of prednisolone
Progesterone injections	1	..	
Hydroxy progesterone injection	4	..	
Pyridoxine tablets	1	..	
Riboflavine tablets	2	..	
Shark liver oil (dilute)	1	1	Failed in respect of iodine value
Thiamine hydrochloride injection	11	5	Low B_1 content, contained suspended particles
Vitamin A injection	1	..	
Vitamin A capsules	1	1	Low vitamin A content
Vitamin B tablets (Compound)	3	1	Failed in B_1 content
Yeast tablets	7	4	Failed in description
TOTAL	99	28	

APPENDIX 3—*Contd.*

Biochemistry Department—List of State Drug Samples Tested during the year 1975-76

Names of Drugs	No. Tested	No. Sub-Standard	Reasons for Rejection
Non-Pharmacopoeial			
B Complex capsules	1	..	
B Complex capsules with enzymes	1	1	Failed in respect of amylase activity.
B Complex capsules with other drugs	1	..	
B Complex injection	25	15	Low vitamin B_1 content; contained suspended particles.
B Complex injection with other drugs	5	..	
B Complex Syrup	7	2	Contained precipitated matter
B Complex syrup with enzymes	6	3	Low diastase and pepsin content.
B Complex syrup with other drugs	12	1	Low B_1 content
B Complex tablets	10	4	Low B_1 and B_2 content; failed in description.
B Complex tablets with other drugs	5	2	Low B_1 content; failed in description.
Colloidal Calcium injection with Vitamin D_2 and B_{12}	7	6	Low D_2 content
Contraceptive tablets	15	..	
Enzyme tablets with other durgs	1	1	Low diastase content
Multivitamin capsules with other drugs	2	..	
Multivitamin injection with other drugs	2	..	
Multivitamin Syrup	1	1	Failed in Vitamin A content
Multivitamin Syrup with other drugs	6	3	Low Vitamin A and C content
Multivitamin tablets	18	1	Low vitamin C content
Multivitamin tablets with other drugs	1	..	
Steroid tablets with other drugs	6	..	
Miscellaneous			
Capsule	1	..	
Injection	10	4	Contained precipitated matter/suspended particles.
Ointment	1	..	
Oral liquid preparations	5	2	Failed in description, High acid value
Tablets	2	..	
TOTAL	151	46	

APPENDIX 3—*Contd.*

Biochemistry Department—List of Imported Drug Samples Tested during the year 1976-77

Name of Drugs	No. Tested	No. Sub-Standard	Reasons for Rejection
Pharmacopoeial			
Ascorbic acid	1	..	
Choline bitartrate	1	..	
Cyanocobalamin	1	1	Low assay value
Dexamethasone	5	..	
Folic acid	1	..	
Ethisterone	1	..	
Hydrocortisone acetate	1	..	
Inositol	3	..	
Lynestrenol	1	..	
Lysine monohydrochloride	1	..	
Menadione	1	1	Sample found to be of menadione Sodium bisulphite
Methandienone	1	..	
Nandrolone phenyl propionate	1	..	
Pancreatin	7	1	Failed in amylolytic activity
Pepsin	8	1	Sample was oily liquid
Ribofiavine	3	..	
Rutin	2	..	
Testosterone	1	..	
Thiamine mononitrate	1	..	
Vitamin E powder	1	..	
Tocopherol acetate	1	..	
Vitamin A acetate	1	..	
	44	4	

APPENDIX 3—*Contd.*

Biochemistry Department—List of Drug Samples (Statutory/Survey/Miscellaneous) Tested during the year 1976-77

Name of Drugs	No. Tested	No. Sub-Standard	Reasons for rejection
	Pharmacopoeial		
Acetomenadione tablets	1	..	
Ascorbic acid injection	1	1	Contained sedimented matter
Ascorbic acid tablets	12	4	Low content, failed in weight variation and description.
Betamethasone tablets	1	..	
Cyanocobalamin injection	19	13	Low and high cyanocobalamin content and pH values; Failed in net content; contained suspended particles.
Dexamethasone sodium phosphate injection.	4	..	
Dexamethasone tablets	38	28	Spurious(1); Low content and failed in weight variation.
Diethylstilbestrol tablets	5	..	
Folic acid	1	..	
Folic acid tablets	2	..	
Hyaluronidase injection	1	..	
Hydrocortisone acetate ointment	1	..	
Hydroxyprogesterone caproate injection.	3	..	
Insulin injection	3	2	Turbid solution
Insulin Zinc suspension injection	3	1	Contained foreign particles
Liver injection	19	3	Low total solid and high protein nitrogen content.
Nandrolone phenyl propionate	3	..	
Nicotinamide tablets	1	..	
Prednisolone tablets	59	21	Spurious (12); Contain prednisone and hydrocortisone acetate. Failed in description instead of prednisolone;.
Pyridoxine hydrochloride injection	2	2	Failed in net content; contained suspended particles.
Pyridoxine tablets	1	..	
Riboflavine tablets	9	..	
Testosterone enanthate injection	1	..	

Biochemistry Department— List of Drug Samples (Statutory/Survey/ Miscellaneous) Tested during the year 1976-77

Name of Drugs	No. Tested	No. Sub-Standard	Reasons for Rejection
Thiamine hydrochloride injection	12	6	Contained suspended particles.
Thiamine compound tablets	14	1	Cracked coating of the tablets.
Thiamine hydrochloride tablets	1	..	
Triamcinolone tablets	1	..	
Vitamin A&D capsules	2	2	Low vitamin A content
Yeast tablets	11	1	Soft and moist tablets
Non-Pharmacopoeial			
B Complex capsules	6	1	Low vitamin B_1 content
B Complex injection	64	46	Contained precipitated matter/ suspended particles.
B Complex oral liquid	28	2	Low B_1 and B_{12} content
B Complex oral liquid with enzymes	11	5	Failed in diastase and pepsin activity; Low Vitamin B_1 content.
B Complex oral liquid with other drugs.	36	10	Cho ine chloride absent, Low Vitamin B_1, B_2, B_6 and nicotinamide and phosphorus content.
B Complex tablets	13	2	Low Vit B_1 and B_2 content
B Complex tablets with enzymes	1	1	Low diastase activity and infested with fungus.
B Complex tablets with other drugs.	4	1	Failed in B_1 content
Colloidal calcium injection with Vitamin D_2, D_3.	5	5	Low Vit D_2, D_3 content
Colloidal calcium injection with Vitamin D_2/D_3 and B_{12}	14	11	Low Vit D_2, D_3 content
Contraceptive tablets	12	..	
Multivitamin capsules	4	1	Failed in Vitamin A content
Multivitamin capsules with other drugs.	6	3	Failed in Vitamin C, folic acid and ferrous fumarate content.
Multivitamin oral liquid	11	8	Low Vitamin A, D and C content. Contained precipitated matter.

APPENDIX 3—*Concld.*

Biochemistry Department—List of Drug Samples (Statutory/Survey/Miscellaneous) Tested during the year 1976-77

Name of Drugs	No. Tested	No. Sub-Standard	Reasons for Rejection
Multivitamin oral liquid with other drugs.	35	17	Low vitamin A and D_2 content; Folic acid absent.
Multivitamin tablets . .	16	10	Failed in description; Low Vitamin A, B and C content.
Multivitamin A with other drugs	10	5	Failed in description; Vitamin B_6 absent.
Steroid tablets with other drugs	5	3	High prednisolone content; Failed in description and Salicylic acid limits.
Miscellaneous			
Capsules	4	1	Low Vitamin C content
Eye/ear drops . . .	2	..	
Injections	8	..	
Ointments	4	..	
Oral liquids	13	..	
Tablests/powder . . .	17	2	Failed in pepsin and diastase activity.

APPENDIX 4

Nature of Examinations and Tests carried out in the Department of Pharmacology during 1974-75

Nature of Test	Names of drugs	No. examined	No. found sub-standard	Reasons for rejection
Physical Character	ACTH	1		
	Adrenaline Inj.	4		
	A.C.D. solution	4	2	Particles
	Ampicillin sodium	5		
	Bi Glu Dox	2		
	Calcium Gluconate Inj.	1		
	Crystalline Penicillin	4		
	Chloramphenicol	4		
	Chloramphenicol	8		
	Dextrose Inj.	71	50	Particles
	Dextrose & sodium chloride Inj.	51	41	Particles
	Gentamycin	2		
	Griseofulvin	2		
	Erythromycin stearate	6		
	Ext Post Pituitary Inj.	44	1	Below net content
	Liver Injection	14		
	Lincomycin HCl	1		
	Mitomycin	1		
	Neomycin	4		
	Noradrine	1		
	Omnadin	1		
	Oxytetracycline	23		
	Periston-N	1	1	Particles
	Procaine Benzyl Penicillin	3		
	Procaine pencillin	6		
	Sodium Chloride Inj.	28	22	Particles
	Sodium Lactate Inj.	6	3	Particles
	Streptopenicillin	28		
	Streptomycin	7		
	Tetracycline HCl	2		
	Thiamine HCl	2		
	Troleandomycin	1		
	Reverin	1		
	Water for Injection	32	17	Particles
		371	137	

APPENDIX 4—*Contd.*

Nature of Examinations and Tests carried out in the Department of Pharmacology during 1974-75

Nature of Test	Names of drugs	No. examined	No. found sub-standard	Reasons for Rejection
Toxicity	Ampicillin sodium	5		
	ACTH	1		
	Bi Glu Dox	2		
	Chloramphenicol	4		
	Crystalline Penicillin	4		
	Chloramphenicol	8		
	Erythromycin Stearate	6		
	Gentamycin	2		
	Griseofulvin	2		
	Liver Injection	14		
	Lincomycin HCl	1		
	Mitomycin C	1		
	Neomycin	4		
	Omnadin	1		
	Oxytetracycline	23		
	Procaine Penicillin	6		
	Procaine Benzyl Penicillin	3		
	Reverin	1		
	Streptopenicillin	28		
	Streptomycin	7		
	Tetracycline	2		
	Troleandomycin	1		
	Thiamine HCl	2		
		128		
Pyrogen	Ampicillin sodium	5		
	ACTH	1		
	ACD Solution	2		
	Bi Glu Dox	2		
	Calcium Gluconate Inj.	1		
	Crystalline Penicillin	4		
	Chloramphenicol	4		
	Dextrose Inj.	21	2	Pyrogenic
	Dextrose & Sodium Chloride Inj.	10		
	Mitomycin C	1		
	Oxytetracycline	21		
	Procaine Penicillin	6		
	Procaine Benzyl Penicillin	3		
	Reverin	1		
	Sodium Lactate Inj.	3		
	Sodium Chloride Inj.	6		
	Streptopenicillin	28		

APPENDIX 4—*Contd.*

Nature of Examinations and Tests carried out in the Department of Pharmacology during 1974-75

Nature of Test	Names of drugs	No. Examined	No. found Sub-Standard	Reasons for Rejection
	Streptomycin	7		
	Tetracycline HCl	1		
	Water for Inj.	15		
		142	2	
Test for Histamine like substances or Depressor Substances	Chloramphenicol	4		
	Liver Inj.	3		
	Oxytetracycline	21		
	Reverin	1		
	Streptomycin	7		
	Tetracycline HCl	1		
		37		
Assay	ACTH	1		
	Adrenaline	4		
	Ext. Post. Pituitary Inj.	44	1	Low potency
		49	1	
Pressor Activity	ACTH	1		
	Adrenaline	4		
	Ext. Post. Pituitary Inj.	44		
		49		
pH of the Solution	ACTH	1		
	Adrenaline	4		
	Ext. Post. Pituitary Inj.	44		
		49		
Chemical Test	Calcium Gluconate Inj.	1		
	Dextrose Inj.	1		
	Water for Inj.	2	1	
		4	1	

APPENDIX 4—*Contd.*

Nature of Examinations and Tests carried out in the Department of Pharmacology during 1975-76

Nature of Test	Names of drugs	No Examined	No found Sub-standard	Reasons for Rejection
Physical Character	A.C.D. Solution	2		
	Adrenaline	3		
	ACTH	1		
	Ampicillin sodium	2		
	Benzyl Penicillin	5		
	Calcium with vitamin C	1		
	Chloroquine Phosphate	1		
	Chloramphenicol	8		
	Calcium Gluconate Inj.	8	6	Particles
	Cycloserine	2		
	Dextrose Inj.	19	8	Particles
	Dextraven	1	1	Particles
	Ext. Post. Pituitary Lobe	13		
	Framycetin sulphate	1		
	Griseofulvin	6		
	Gentamycin Sulphate	4		
	Haemaccel	1		
	Heparin	2		
	Insulin	1		
	Liver Inj,	12	1	Particles
	Methergin	1		
	Neurabol H	2		
	Neomycin	3		
	Omnadin	1		
	Oxytetracycline	13		
	Procaine Benzyl Penicillin	4		
	Procaine Penicillin	4		
	Reverin	1		
	Sodium Chloride and Dextrose Inj.	23	16	Particles
	Sodium Chloride Inj.	11	9	Particles
	Streptomycin	3		
	Streptopenicillin	26		
	Sodium Stibogluconate	2		
	Sodium Antimony gluconate	3		
	Tetracycline	5		
	Thiamine HCl	1		
	Vitamin B_1	2		
	Water for Inj.	49	40	Particles
		247	81	

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APPENDIX 4—*Contd.*

Nature of Examinations and Tests carried out in the Department of Pharmacology during 1975-76

Nature of Test	Names of Drugs	No Examined	No. found Sub-standard	Reasons for Rejection
Toxicity	Ampicillin sodium	2		
	ACTH	1		
	Benzyl Penicillin	5		
	Chloramphenicol	8		
	Chloroquine Phosphate	4		
	Calcium with Vit. C	1		
	Cycloserine	2		
	Framycetin Sulphate	1		
	Griseofulvin	6		
	Insulin	1		
	Liver Inj.	11		
	Methergin	1		
	Neomycin	3		
	Neurabol H	2		
	Oxytetracycline	13		
	Oxytetracycline	1		
	Omnadin	1		
	Procaine Benzyl Penicillin	4		
	Procaine Penicillin	4		
	Reverin	1		
	Streptopenicillin	26		
	Sodium antimony gluconate	3		
	Sodium Stibugluconate	2		
	Streptomycin	3		
	Vitamin B1	2		
		109		
Pyrogen	ACTH	1		
	Ampicillin Sodium	2		
	ACD Solution	2		
	Benzyl Penicillin	4		
	Chloramphenicol	8		
	Calcium Gluconate	2		
	Dextrose Inj.	11		
	Haemaccel	1		
	Heparin	2		
	Liver Inj.	11		
	Omnadin	1		
	Oxytetracycline	13		
	Procaine Penicillin	4		
	Procaine Benzyl Penicillin	4		
	Reverin	1		
	Streptomycin	3		
	Sodium Chloride & Dextrose Injection.	7		
	Sodium Chloride Inj.	2		

APPENDIX 4—*Contd.*

Nature of Examinations and Tests carried out in the Department of Pharmacology during 1975-76

Nature of Test	Names of Drugs	No. Examined	No found Sub-standard	Reasons for Rejection
	Streptopenicillin	26		
	Water for Inj.	9		
		115		
Histaminelike Substances	Chloramphenicol	4		
	Heparin	2		
	Liver Inj.	1		
	Oxytetracycline	12		
	Streptomycin	3		
		22		
Assay	ACTH	1		
	Adrenaline	3		
	Ext. Post. Pituitary Inj.	13		
	Heparin	2		
		19		
Pressor Activity	ACTH	1		
	Adrenaline	1		
	Ext. Post. Pituitary Inj.	13		
	Heparin	2		
		17		
pH of the Solution	ACTH	1		
	Adrenaline	3		
	Ext. Post. Pituitary Inj.	13		
		17		
Chemical Test	ACD Solution	2		
	Calcium Gluconate Inj.	8		
	Dextrose Inj.	19		
	Dextraven	1		
	Sodium Chloride & Dextrose Inj.	23		
	Sodium Chloride Inj.	11		
	Water for Inj.	49	5	Oxidisable matters—4 Ammonia—1
		113	5	

APPENDIX 4—*Contd.*

Nature of Examinations and Tests carried out in the Department of Pharmacology during 1976-77

Nature of Test	Names of drugs	No. examined	No. found Sub-standard	Reasons for Rejection
Physical Character	Ampicillin sodium	3		
	Adrenaline	5		
	ACD Solution	2		
	Atropine Sulphate	1		
	ACTH	1		
	Benzyl Penicillin	5		
	Coramine	1		
	Chloroquine Phosphate	1		
	Calcium Gluconate Inj.	6	3	Particles
	Chloramphenicol	4		
	Cycloserine	2		
	Dextrose Injection	42	13	Particles—12 Transparency of the container-1
	Dextrose & Sodium Chloride Inj.	33	21	Particles
	Dextraven	1	1	Particle
	Diovol	1		
	Ext. Post. Pituitary	21		
	Framycetin sulphate	1		
	Griseofulvin	13		
	Gentamycin	5		
	Heparin	1		
	Liver Inj.	19		
	Lignocaine Hydrochloride	1		
	Lomodex	1	1	Particle
	Lindent	1		
	Lincomycin HCl	1		
	Mannitol	2		
	Neomycin	4		
	Oxytetracycline	9		
	Procaine Penicillin	4		
	Procaine Benzyl Pencicillin	7		
	Pethidine HCl	2		
	Reverin	3		
	Rybarium	1	1	Particle
	Ringer Lactate	1	1	Particle
	Sodium Chloride Inj.	13	7	Particles
	Sodium Lactate Inj.	6	5	Particles
	Streptopenicillin	10		
	Streptomycin	12		
	Scolin	2		
	Sodium Stibogluconate	6		
	Sodium Antimony Gluconate	1		
	Redisol	1		
	Water for Inj.	62	23	Particles—22 Net content—1
	Tetracycline HCl	6		
	Tetracycline phosphate complex	1		
		325	76	

APPENDIX 4—*Contd.*

Nature of Examinations and Tests carried out in the Department of Pharmacology during 1976-77

Nature of Test	Names of Drugs	No. Examined	No found Sub-standard	Reasons for Rejection
Toxicity	Ampicillin Sodium	3		
	Adrenaline (Lignocaine)	1		
	ACTH	1		
	Atropine sulphate	1		
	Benzyl Penicillin	5		
	Coramine	1		
	Chloroquine Phosphate	1		
	Cycloserine	2		
	Chloramphenicol	4		
	Diovol	1		
	Framycetin sulphate	1		
	Griseofulvin	13		
	Gentamycin	5		
	Lineomycin HCl	1		
	Lindent	1		
	Liver Inj.	19		
	Lignocaine HCl	1		
	Oxytetracycline	9		
	Pethidine HCl	2		
	Procaine Penicillin	4		
	Procaine Benzyl Penicillin	7		
	Reverin	3		
	Redisol	1		
	Sodium Stibogluconate	6	4	Toxic
	Sodium Antimony gluconate	1		
	Scolin	2		
	Streptomycin	12		
	Streptopenicillin	10		
	Neomycin	4		
	Tetracycline Phosphate Comp	1		
	Tetracycline	6		
		229	4	
Pyrogen	ACD Solution	2		
	ACTH	1		
	Ampicillin	2		
	Benzyl Penicillin	5		
	Chloramphenicol	3		
	Cal. Gluconate Inj.	3		
	Dextrose Inj.	29		
	Dextrose & Sodium Chloride Inj.	11		
	Heparin	1		
	Gentamycin	1		

APPENDIX 4—*Contd.*

Nature of Examinations and Tests carried out in the Department of Pharmacology during 1976-77

Nature of Test	Names of Drugs	No. examined	No. found Sub-standard	Reasons for Rejection
Pyrogen—Contd.	Mannitol	2		
	Oxytetracycline	9		
	Procaine Penicillin	4		
	Procaine Benzyl Penicillin	7		
	Streptopenicillin	10		
	Sodium Lactate Inj.	1		
	Sodium Chloride Inj.	6		
	Streptomycin	12		
	Tetracycline HCl	1		
	Water for Inj.	38		
		148		
Test for Histamine like Substances or Depressor Substances	Chloramphenicol	3		
	Liver Inj.	6		
	Heparin	1		
	Oxytetracycline	9		
	Streptomycin	12		
	Tetracycline	1		
		32		
Assay	ACTH	1		
	Adrenaline	4		
	Ext. Post. Pituitary Inj.	21		
	Heparin	1		
		27		
Pressor Activity	ACTH	1		
	Adrenaline	4		
	Ext. Post. Pituitary Inj.	21		
	Heparin	1		
		27		
pH of the Solution	ACTH	1		
	Adrenaline	4		
	Ext. Post. Pituitary Inj.	21		
		26		

APPENDIX 4—*Concld.*

Nature of Examinations and Tests carried out in the Department of Pharmacology during 1976-77

Nature of Tests	Names of Drugs	No. examined	No. found Sub-standard	Reasons for Rejection
Chemical Test	ACD Solution . . .	2		
	Calcium Gluconate Inj. .	6		
	Dextrose Inj. . . .	42	3	Low potency
	Dextrose & Sodium Chloride Inj.	33	1	Heavy metal
	Dextraven . . .	1		
	Sodium Lactate Inj. . .	6		
	Sodium Chloride Inj. . .	13		
	Water for Inj. . . .	62		
		165	5	

APPENDIX 5

Bacteriology Department—Statement of Samples tested and found sub-standard during 1974-75

Source of Receipt	Names of Samples	No. Tested	No. Sub-standard	Reasons for Rejection
Customs (Imported)	Ampicillin	4		
	Chloramphenicol	1		
	Erythromycin	1		
	Gentamycin	2	1	Potency low
	Lincomycin	2		
	Mitomycin	1	1	Potency
	Multivitamin Pediatric Drop	1	1	Content
	Neomycin Sulphate	4		
	Rifamycin	1		
	Streptomycin Sulphate	7		
	Penicillin Oral	1		
	Tetracycline	3		
	Troleandomycin	1		
		29	3	
State Drug Inspectors	Chloramphenicol (Oral)	54	12	Content
	do Injectable	1		
	Chloramphenicol & Streptomycin Oral	23	1	Content
	do. Injectable	2		
	Chlortetracycline	2		
	Doxycycline	2		
	Disinfectant Fluid	5	5	R.W. Co-efficient
	Erythromycin	12		
	Oxytetracycline (Oral)	29	8	Content - 6 Description - 2
	Oxytetracycline Injectable	11	1	Description - 1
	Penicillin (Oral).	15	5	Content - 4 Description - 1
	Penicillin Injectable	36	1	Content
	Penicillin & Streptomycin	9		
	Gention Violet	1		
	Neomycin sulphate	2		
	Preparation containing B12 (Oral).	41	2	B12 content
	Preparation containing B12 (Injectable)	22	3	B12 content
	Preparation containing Pantothenate (Oral).	13	2	Content
	Streptomycin (Oral)	16	1	Potency Low
	Streptomycin Injectable	12		
	Surgical Suture	1		
	Tetracycline	62	8	Content
		371	49	

APPENDIX 5—*Contd.*

Bacteriology Department—Statement of Samples tested and found sub-standard during 1974-75

Source of receipt	Names of Samples	No. Tested	No. Sub-standard	Reasons for rejection
	Samples Tested for Sterility			
State Drug Inspectors	Atropine Sulphate	8		
	B Complex Inj.	18	5	Particles - 4 Non Sterile - 1
	Bi - Glu - Dox - Inj.	1		
	Calcium Gluconate Inj.	3	3	Particles
	Coramine Inj.	5		
	Decadron Phosphate Inj.	2		
	Dextrose Inj.	82	50	Non Sterile - 4 Particles - 46
	Morphine Injection	6		
	Post. Pituitary Inj.	21	1	Particles
	Pethidine Inj.	8		
	Normal Saline	6	4	Particles
	Sodium Lactate Inj.	3		
	Tripalgin Inj.	2		
	Sodium Chloride & Dextrose Inj.	30	21	Particles
	Water for Inj.	19	4	Particles
		214	88	
Miscellaneous	Doxycycline	2		
	Oxytetracycline (Oral)	1	1	Content
	Penicillin	2		
	Tetracycline (Oral)	1		
		6	1	

APPENDIX 5—*Contd.*

Bacteriology Department—Statement of Samples tested and found sub-standard during 1975-76

Source Receipt	Names of Samples	No. Tested	No. Sub-standard	Reasons for Rejection
Customs (Imported)	Ampicillin	2		
	Colistin Sulphate	1		
	Cloxacillin Sodium	1		
	Chloramphenicol	3		
	Doxycycline	12		
	Framycetin	2		
	Gentamycin	3		
	Mitomycin C	1	1	Potency Low
	Omnadin	1		
	Rifampicin	2		
	Subamycin Granules	2	2	Potency low
	Neomycin	4		
	Streptomycin	1		
	Tetracycline	12		
		47	3	
State Drug Inspectors	Ampicillin	1		
	Chloramphenicol	41	7	Content
	Chloramphenicol and Streptomycin.	17	1	Content
	Disinfectant fluid	2	2	R.W. Co efficient
	Erythromycin	3		
	Garamycin	1		
	Neomycin sulphate	2		
	Omnamycin	1		
	Oxytetracycline (Oral)	12	2	Content
	Oxytetracycline Injectable	8		
	Penicillin & Streptomycin	19		
	Penicillin (Oral)	10	1	Content
	Penicillin Injectable	12		
	Preparation containing Vitamin B12 (Oral).	16	1	B12 content
	Preparation containing Vitamin B12 Injectable	20	3	B12 content
	Preparations containing Pantothenate (Oral).	7		
	Rolitetracycline	2		
	Streptomycin Oral	8		
	Streptomycin Injectable	5		
	Tetracycline	41	9	Content - 7 Description - 2
		228	26	

APPENDIX 5—*Contd.*

Bacteriology Department— Statement of Samples tested and found sub-standard during 1975-76

Source Receipt	Names of Samples	No. Tested	No. Sub-standard	Reasons for Rejection
	Samples Tested for Sterility			
State Drug Inspectors	Aminophylline Inj.	1	1	Particles
	Adrenaline Inj.	2		
	B. Complex Inj.	3	1	Particles
	Bi-glu-Dox Inj.	1		
	Calcium Gluconate Inj.	3	1	Particles
	Coramine Inj.	2		
	Dextrose & Sodium Chloride Inj.	6	4	Particles
	Dextrose Inj.	16	3	Particles
	Eye Cold Lotion	1		
	Heparin Inj.	2		
	Morphine Inj.	3		
	Normal Saline	1		
	Pethidine Inj.	10		
	Proluton Depot	1		
	Post. Pituitary Inj.	5		
	Sodium Chloride Inj.	10	3	Non sterile - 1 Particles - 2
	Sterile Absorbent Cotton	1		
	Sodium Antimony Gluconate	3		
	Thiamine HCl Inj.	1		
	Water for Inj.	40	15	Particles - 13 Non-sterile - 2
		112	28	
Miscellaneous	Germisol	1		

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APPENDIX 5—*Contd.*

Bacteriology Department—Statement of Samples tested and found sub-standard during 1976-77

Source of receipt	Names of samples	No. tested	No. sub-standard	Reasons for rejection
Customs (Imported)	Ampicillin	1		
	Cyclophosphamide Inj.	1		
	Doxycycline	24		
	Gentamycin	4		
	Neomycin	4		
	PAM Injection	1		
	Pectin	1		
	Rifamycin	7		
	Tetracycline	5		
	Tetracycline Phosphate Complex	4		
		52		
State Drugs Inspector	Chloramphenicol (Oral)	72	6	Spurious - 4 Content - 2
	Chloramphenicol Injectable	7		
	Chloramphenicol & Streptomycin	24	3	Spurious
	Chlortetracycline	1		
	Doxycline	4		
	Disinfectant fluid	38	37	R.W. Coefficient
	Gentamycin	1		
	Garamycin	1		
	Oxytetracycline (Oral)	15	2	Content
	Oxytetracycline Injectable	4		
	Penicillin (Oral)	22	2	Content
	Penicillin Injectable	37	2	Content
	Preparations containing Vitamin B12 (Oral)	53	2	B12 content
	Preparations containing Vitamin B12 Injectable	28	1	B12 content
	Preparations containing Pantothenate (Oral)	9	3	Content
	Preparations containing Pantothenate Injectable	3		

APPENDIX 5—*Concld.*

Bacteriology Department—Statement of Samples tested and found sub-standard during 1976-77

Source of receipt	Names of samples	No. tested	No. sub-standard	Reasons for rejection
State Drug Inspector	Rifampicin	2		
	Rolitetracycline	1		
	Reverin	4		
	Neomycin	4	1	Potency low
	Streptomycin (Oral)	10		
	Streptomycin Injectable	11		
	Tetracycline (Oral)	78	9	Description - 1 Content - 2 Spurious - 6
	Tetracycline Injectable	2		
	Tetracycline Phosphate Complex	2		
		433	68	
	Samples tested for Sterility			
State Drug Inspector	Atropine Sulphate Inj.	5		
	Cyanocobalamin Inj.	14		
	Chloroquine Phosphate Inj.	12		
	Calcium Gluconate Inj.	5		
	Dextrose Inj.	30	2	Fungus - 1 Non sterile - 1
	Dextrose & sodium chloride Inj.	18		
	Durabolin Inj.	2		
	Decadron Phosphate Inj.	2		
	Eye Cold Lotion	1		
	Injection of Milk Iodine	2	1	Sterility
	Insulin Injection	4	1	Non-sterile
	Morphine Inj.	7		
	Normal Saline	4		
	Others	20		
	Post. Pituitary Inj.	6		
	Pethidine HCl Inj.	15		
	Thiamine HCl Inj.	9		
	Sodium Chloride Inj.	7	1	Non sterile
	Vitamin B Complex	9		
	Water for Inj.	59	7	Non-sterile
		231	12	

APPENDIX 6

Pharmacognosy Department—List of Imported Drugs tested and found sub-standard during 1974-75

Names of drugs	No. tested	No. Sub-standard	Reasons for rejection
Gum Benzoin B.P.C. .	5	3	Alcohol insoluble matter and total balsamic acid does not conform to B.P.C.
Cinnammon I.P. . .	1	1	Description does not conform to I.P.
	6	4	

Pharmacognosy Department—List of State Drug Samples tested and found sub-standard during 1974-75

Names of drugs	No. tested	No. Sub-standard	Reasons for rejection
Promazine Hydrochloride Tabs N.F. . . .	1	1	Identified as Promethazine H Cl

Pharmacognosy Department—List of State Drug Samples tested and found sub-standard during 1975-76

Chlorodyne B.P.C. .	2	1	Wt/Ml content of morphine and alcohol does not conform.
Intacep Tabs . . .	1	1	Infested with fungus.
Itchical (Powder) . .	1	1	Active ingredients found absent
Saffron . . .	6	5	Identification, odour, colour, ash, alcohol extractive and moisture content do not conform to B.P.C.
Strong Ginger Tincture I.P.	1	1	Total solids and wt/ml do not conform to I.P.
Vitamin B Complex Tabs	4	3	Due to spots and denatured yeast cells.
	20	15	

Pharmacognosy Department—List of Drug Control Administration (Zonal Samples) tested and found sub-standard during 1974-75

Names of drugs	No. tested	No. Sub-standard	Reasons for rejection
Absorbent Cotton I.P.	1	1	Contains dead insects.
Tr. Benzoin Co. B.P.	1	1	Contains resinous clottings of different masses.
	2	2	

Pharmacognosy Department—List of Drug Control Administration (Zonal Samples) tested and found sub-standard during 1975-76

Gripe Water	1	1	Infested with fungus.
Tr. Benzoin Co. I.P.	1	1	Total solids and total balsamic acid do not conform to I.P.
	2	2	

Pharmacognosy Department—List of Drug Control Administration (Zonal Samples) tested and found sub-standard during 1976-77

Absorbent Gauze I.P.	8	7	Selvedge, length and fluorescence do not conform.
Aluminex	1	1	Belladonna tincture found absent.
Absorbent Cotton Wool I.P.	4	2	Fluorescence test does not conform.
Bandages	1	1	Fluorescence test does not conform.
Caflon (Cough syrup)	1	1	Active ingredients found absent.
Compound Benzoin Tincture I.P.	2	1	Total balsamic acid does not conform.
Dextraven	1	1	Infested with fungus.
Deltolive	1	1	Olive Oil found absent.
Gripenil	1	1	Contaminated with filamentous algae with spores.
Gripe Water	1	1	Infested with fungus.
	21	17	

APPENDIX 6—*Concld.*

Pharmacognosy Department—List of samples received from Courts of Law tested and found sub-standard during 1976-77

Names of drugs	No. tested	No. Sub-standard	Reasons for rejection
Aqua Camphorae Conc I.P.	1	1	Camphor and alcohol content do not conform to I.P.
Aqua Anisi Conc B.P.C. .	1	1	Wt/ml and alcohol content do not conform to B.P.C.
	2	2	

Pharmacognosy Department—List of State Drug Samples tested and found sub-standard during 1976-77

Alkasen (Ayurvedic product).	1	1	Citric acid absent.
Citrin	1	1	Citric acid absent.
Cough Syrup . . .	1	1	Infested with fungus.
Controacep (Homoeopathic).	1	1	Asafoetida and Natmur absent.
Exi-Cure (Homoeopathic)	1	1	Salicylic acid and phenol absent.
Jirna Sudha (Powder) .	1	1	Di-iodohydroxyquinoline and sulfaguanidine absent.
Prednisolone Tablets .	1	1	Infested with fungus.
Primozyme . . .	1	1	Active ingredients absent.
Sulphadimidine B Vet C .	2	2	Infested with fungus.
Sulphaguanidine Tabs. .	1	1	Infested with fungus.
	11	11	

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